CLAIMS

1. A method for evaluating the potential efficacy of an EGFR-targeting therapeutic agent for the treatment of cancer in a patient comprising determining the sequence of a polymorphism in one or both EGFR genes in the patient.

2. The method of claim 1, wherein the polymorphism is at, or in linkage disequilibrium with, a nucleotide position selected from the group consisting of nucleotide positions -1435, -1300, -1249, -1227, -761, -650, -544, -486, -216, -191, 169, and 2034.

3. The method of claim 2, wherein the polymorphism is, or is in linkage disequilibrium with, a polymorphism selected from the consisting of –1435 C>T, -1300 G>A, -1249 G>A, -1227 G>A, -761 C>A, -650 G>A, -544 G>A, -486 C>A, -216 G>T, -191 C>A, 169 G>T, and 2034 G>A.

4. The method of claim 1, further comprising determining the sequence of at least two polymorphisms in one or both EGFR genes in the patient.

5. The method of claim 1, wherein the EGFR-targeting therapeutic agent is an EGFR-tyrosine kinase inhibitor.

6. The method of claim 5, wherein the EGFR-tyrosine kinase inhibitor is gefitinib or erlotinib.

7. The method of claim 1, wherein the EGFR-targeting therapeutic agent is a monoclonal antibody.

8. The method of claim 7, wherein the monoclonal antibody is cetuximab.

9. The method of claim 3, wherein the polymorphism is –216 G>T.

10. The method of claim 9, wherein a T at position –216 on an allele is an indicator of higher expression of EGFR protein, and further wherein the higher expression of EGFR protein is an indicator of decreased efficacy of the EGFR-targeting therapeutic agent.

11. The method of claim 1, further comprising determining the sequence of a polymorphism in both EGFR genes in the patient.

12. The method of claim 1, wherein determining the sequence of a polymorphism is performed by a hybridization assay.

13. The method of claim 1, wherein determining the sequence of a polymorphism is performed by an allele specific amplification assay.

14. The method of claim 1, wherein determining the sequence of a polymorphism is performed by a sequencing or a microsequencing assay.

15. The method of claim 1, wherein determining the sequence of a polymorphism is performed by digestion with a restriction enzyme.

16. The method of claim 1, further comprising obtaining a sample.

17. The method of claim 16, wherein the sample comprises buccal cells, mononuclear cells, or cancer cells.

18. The method of claim 1, further comprising administering the EGFR-targeting therapeutic agent to the patient.

19. A method for predicting the clinical prognosis for a cancer patient comprising determining the sequence of a polymorphism in one or both EGFR genes in the patient.

20. The method of claim 19, further comprising determining the sequence of a polymorphism in both EGFR genes in the patient.

21. The method of claim 19, wherein the polymorphism is at, or in linkage disequilibrium with, a nucleotide position selected from the group consisting of nucleotide positions -1435, -1300, -1249, -1227, -761, -650, -544, -486, -216, -191, 169, and 2034.

22. The method of claim 21, wherein the polymorphism is, or is in linkage disequilibrium with, a polymorphism selected from the consisting of –1435 C>T, -1300 G>A, -1249 G>A, -1227 G>A, -761 C>A, -650 G>A, -544 G>A, -486 C>A, -216 G>T, -191 C>A, 169 G>T, and 2034 G>A.

23. The method of claim 22, wherein the polymorphism is –216 G>T.

24. The method of claim 23, wherein a T at position –216 on an allele is an indicator of an increased expression of EGFR protein.

25. The method of claim 24, wherein the increased expression of EGFR protein is predictive of poor prognosis.

26. The method of claim 25, wherein the poor prognosis indicates increased resistance to chemotherapy, hormonal therapy, or radiotherapy.

27. The method of claim 25, wherein the poor prognosis indicates increased risk of metastasis.

28. A method for evaluating a patient's risk of toxicity to an EGFR-targeting therapeutic agent comprising determining the sequence of a polymorphism in one or both EGFR genes in the patient.

29. The method of claim 28, wherein the polymorphism is at, or in linkage disequilibrium with, a nucleotide position selected from the group consisting of nucleotide positions -1435, -1300, -1249, -1227, -761, -650, -544, -486, -216, -191, 169, and 2034.

30. The method of claim 29, wherein the polymorphism is, or is in linkage disequilibrium with, a polymorphism selected from the consisting of –1435 C>T, -1300 G>A, -1249 G>A, -1227 G>A, -761 C>A, -650 G>A, -544 G>A, -486 C>A, -216 G>T, -191 C>A, 169 G>T, and 2034 G>A.

31. The method of claim 30, wherein the polymorphism is –216 G>T.

32. The method of claim 31, wherein a T at position –216 on one or both alleles is an indicator of decreased toxicity of the EGFR-targeting therapeutic agent.

33. The method of claim 28, further comprising determining the sequence of a polymorphism in both EGFR genes in the patient.

34. A method for predicting the expression level of EGFR in a cell comprising determining the sequence at position –216 in one or both alleles of the EGFR gene in the cell, wherein a T at position –216 in one or both alleles is indicative of a higher expression level.

35. A method for evaluating the potential efficacy of an EGFR-targeting therapeutic agent for the treatment of a disease associated with the dysregulation of EGFR in a patient comprising determining the sequence of a polymorphism in one or both EGFR genes in the patient.

36. A kit for evaluating the potential efficacy of an EGFR-targeting therapeutic agent in a patient comprising a nucleic acid for determining the sequence of a polymorphism in an EGFR gene locus.

37. The kit of claim 36, wherein the nucleic acid is a primer for amplifying a polymorphism at a nucleotide position selected from the group consisting of -1435, -1300, -1249, -1227, -761, -650, -544, -486, -216, -191, 169, and 2034.

38. The kit of claim 36, wherein the nucleic acid is a specific hybridization probe designed to detect a polymorphism at a nucleotide position selected from the group consisting of -1435, -1300, -1249, -1227, -761, -650, -544, -486, -216, -191, 169, and 2034.

39. The kit of claim 38, wherein the specific hybridization probe is comprised in an oligonucleotide array or microarray.

40. A kit for evaluating the potential efficacy of an EGFR-targeting therapeutic agent in a patient comprising a restriction enzyme for determining the sequence of a polymorphism in an EGFR gene locus.